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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,701	06/27/2003	Mark V. Vandewalle	5490-000283	9681

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EXAMINER
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ARAJ, MICHAEL J

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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07/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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## Office Action Summary

Application No.

10/608,701

Applicant(s)

VANDEWALLE, MARK V.

Examiner

Michael J. Araj

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13-15,17-30 and 32-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-11,13-15,17,18 and 42-44 is/are allowed.
- 6) ☒ Claim(s) 34-41 is/are rejected.
- 7) ☒ Claim(s) 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Claims**

Claims 1, 3-11, 13-15, 17-30 and 32-45 are pending.

### ***Claim Objections***

Claim 45 is objected to because of the following informalities: It is unclear how the implant can be between a head of the anchor and the intermediate region of the anchor especially if the anchor is below the surface and the implant is above the surface. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

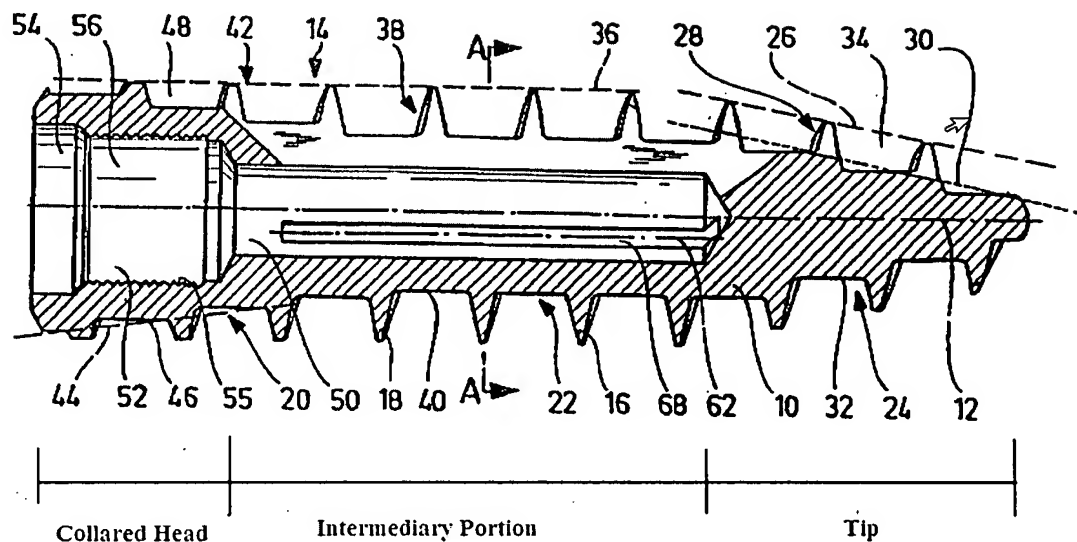
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultheiss et al. (U.S. Patent No. 6,755,835) in view of Wolf (U.S. Patent No. 6,629,977) and further in view Baker et al. (U.S. Patent No. 5,569,251).

Schultheiss et al. discloses the method steps of securing an implant to a bone which includes implanting a bone screw anchor (10) within the bone using a driving tool operable with the head of the anchor; injecting bone cement into a threaded bore extending through the head to at least a portion of the intermediary portion using a

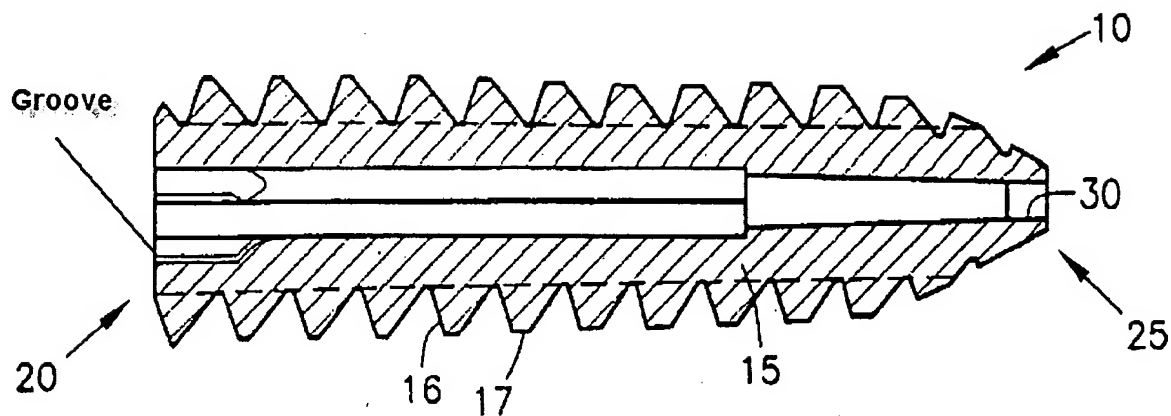
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cement delivery device that allows the anchor to be secured; and securing the implant to the anchor using a threaded fastening device (58) to secure within the bore (see Figure 6). Schultheiss et al. also discloses that the internally threaded portion (55) is inherently protected during the ejecting step, the delivery device (76) is connected to the internal thread of the anchor to protect the threads from being contaminated with bone cement during the injecting step and the bone cement exits at least one port (68) located on the side of the anchor. Also disclosed is threading a fastening device (58) into the anchor to a depth not beyond a tip (24) of the anchor. Schultheiss et al. also disclose a proximal portion between the head and the intermediary portion where the proximal portion is devoid of external threads and has a diameter that is at least approximately the same as a diameter of the external threads of the intermediary portion. As seen in Figure 1 below the proximal portion of the collared head is non-threaded. Approximately is treated as a very broad term therefor the proximal portion is at least approximately the same diameter of the external threads of the intermediary portion.

**Figure 1**

Schultheiss discloses the claimed invention except for and open tip or a screw head having grooves. Wolf discloses a groove (see Figure 2 below) to receive a driving tool to optimize torque capacity when inserting the device (Paragraph 9). Wolf also discloses an open tip (30) so that a guide pin may be used during delivery and installation (Paragraph 11). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Schultheiss with a head defining a groove as well as an open tip in view of wolf, in order to have a device that can be installed with ease and accuracy.

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**Figure 2**

The combination of Schultheiss et al. and Wolf disclose the claimed invention except for placing an implant over the anchor and fastening the implant to the anchor using a fastening device. Barker et al. disclose the method of placing the implant, in this case a bone plate (12), over the anchors and using a fastening device to the anchor in order to secure the assembly and strengthen the bone (Col. 3, Paragraph 3). It would have been obvious to one skilled in the art at the time the invention was made to combine the method of securing a bone screw anchor system to a bone of Schultheiss et al. and Wolf and applying it with a bone plate in view of Baker et al., in order to have secure support for a damaged bone and allow it to heal accordingly.

### ***Response to Arguments***

Applicant's arguments filed April 19, 2007 have been fully considered but they are not persuasive. It is stated that the disclosed references do not have a fastening device not extending to the intermediate region. Applicant is directed towards Figure 6

of Schultheiss where the fastening device (58) does not extend into the intermediary portion.

***Allowable Subject Matter***

Claims 1,3-11,13-15,17,18 and 42-44 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MJA



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER